REMARKS

This responds to the Office Action mailed on January 19, 2006.

Claims 4 and 14 are canceled without prejudice to their prosecution in another application. Therefore, claims 1-3, 5-13 and 15-44 are now pending in this application. However, claims 21-44 have been withdrawn from consideration by the Examiner as a result of the Restriction Requirement. Thus, claims 1-3, 5-13 and 15-20 are now under examination.

Claims 1 and 11 have been amended. In particular, the language of claims 4 and 14 has been incorporated into claims 1 and 11, respectively. Moreover, the terms "thereby" and "assaying for" have been deleted from claims 1 and 11. In addition, claim language from the preambles of claims 1 and 11 has been recited in the body of these claims to clarify the outcome of the methods. Applicant submits that the subject matter of claims 1 and 11 is supported by the specification and claims as originally filed, and that no new matter has been added to the application.

Specification

The Examiner has objected to certain alleged informalities in the specification.

First, the Examiner has stated that "singlet oxygen" is a member of the genus of "reactive oxygen species." Applicant submits that the specification clearly identifies and explicitly defines what is a "reactive oxygen species," for example, at page 18, lines 4-11. As described in the specification at page 18, lines 4-11, singlet oxygen is not a "reactive oxygen species." Moreover, as stated in the specification, singlet oxygen ($^1O_2$*) is a *substrate* used by antibodies to generate reactive oxygen species (see, e.g., page 20, lines 15-19). Applicant submits that there is no need to amend the entirety of the specification to distinguish singlet oxygen species from the reactive oxygen species because the specification is already clear in this regard. Withdrawal of this objection to the specification is respectfully requested.

Second, the Examiner has stated that the sentence at page 23, lines 6-7 is indefinite. This sentence has been amended to recite the following: "Upon oxidation of such chemical probes, oxidation products such as ketones, aldehydes, ethers and related products are

generated." Applicant submits that this sentence is clear and definite and requests withdrawal of this objection to the specification.

§112 Rejection of the Claims

Claims 1-20 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Applicant submits that indefiniteness depends on whether one of skill in the art would understand the scope of the claim when the claim is read in light of the specification. *North American Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333 (Fed. Cir. 1993). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Miles Laboratories Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993).

Claim 1 is now directed to a method for detecting an antibody response in a mammal comprising: (a) administering to the mammal a chemical probe for an antibody-generated reactive oxygen species; (b) obtaining a sample from the mammal; and (c) analyzing the sample for an oxidized chemical probe to detect whether there is an antibody response in the mammal; wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons.

Claim 11 is now directed to a method for detecting an antibody-generated inflammatory response in a mammal comprising: (a) administering to the mammal a chemical probe for an antibody-generated reactive oxygen species; (b) obtaining a sample from the mammal; and (c) analyzing the sample for an oxidized chemical probe to detect whether there is an antibody-generated inflammatory response in the mammal; wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons.

Terms that the Examiner asserts are indefinite are listed separately below.

The method outcome

The Examiner has asserted that the preamble of claims 1 and 11 does not appear to correspond with the method outcome. In particular, the Examiner has stated that while the preamble of claim 1 recites "a method for assaying for an immunological response," it not clear

how merely "analyzing the sample for an oxidized chemical probe" amounts to a method for assaying for an immunological response.

Applicant submits that the Examiner has identified one surprising feature of the invention – the recognition that antibodies can enzymatically generate reactive oxygen species such as hydrogen peroxide and ozone, and detection of such reactive oxygen species is a marker for an antibody response. As described in the specification, all that is needed for detecting an antibody-mediated immunological or inflammatory response is detection of the reactive oxygen species generated by the antibodies (*see, e.g.*, page 15, lines 6-17). Several examples illustrate this feature of the invention. In view of the teachings provided in the specification, Applicant submits that one of skill in the art would understand the scope of the claims and that nothing further is needed.

However, to facilitate their allowance, claims 1 and 11 are now directed to a "method for detecting an antibody response in a mammal" and a "method for detecting an antibody-generated inflammatory response in a mammal," respectively. Moreover, the outcome of these methods is clearly recited near the end of claims 1 and 11. Thus, claim 1 recites "analyzing the sample for an oxidized chemical probe to detect *whether there is an antibody response in the mammal.*" Similarly, claim 11 recites "analyzing the sample for an oxidized chemical probe to detect *whether there is an antibody-generated inflammatory response in the mammal.*" Applicant submits that the outcome of the method is definitely recited in the claims and respectfully urges the Examiner to withdraw this rejection of claims 1-20 under 35 U.S.C. § 112, second paragraph, with respect to any issues relating to the method outcome.

Thereby

The Examiner has stated that use of the term "thereby" in claims 1 and 11 is indefinite. The term "thereby" is now not present in claims 1 and 11. Applicant respectfully requests withdrawal of this rejection of claims 1-20 under 35 U.S.C. § 112, second paragraph, with respect to any issues relating to the term "thereby."

The inflammatory response

The Examiner has stated that no antecedent basis exists for the phrase "the inflammatory response." While Applicant notes that even prior to amendment the preambles of claims 1 and 11 contain antecedent basis for the terms "immunological response" and "inflammatory response," the language of claims 1 and 11 has been further clarified so that no issue relating to a lack of antecedent basis exists.

Applicant respectfully requests withdrawal of this rejection of claims 1-20 under 35 U.S.C. § 112, second paragraph, with respect to any issues relating to the antecedent basis of phrases "immunological response" and "inflammatory response."

§102 Rejection of the Claims

Claims 1-20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Medford et al. (U.S. Patent 5,846,959, "Medford"). According to the Examiner, Medford describes the present methods of assaying for an immunological response. The Examiner cites Medford at col. 4, lines 28-35; col. 4, lines 36-39; and col. 4, lines 48-54 as support for these allegations.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*,

17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

Claim 1 is directed to a method for detecting an antibody response in a mammal comprising: (a) administering to the mammal a chemical probe for an antibody-generated reactive oxygen species; (b) obtaining a sample from the mammal; and (c) analyzing the sample for an oxidized chemical probe to detect whether there is an antibody response in the mammal; wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons.

Claim 11 is directed to a method for detecting an antibody-generated inflammatory response in a mammal comprising: (a) administering to the mammal a chemical probe for an antibody-generated reactive oxygen species; (b) obtaining a sample from the mammal; and (c) analyzing the sample for an oxidized chemical probe to detect whether there is an antibody-generated inflammatory response in the mammal; wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons.

In contrast to the claimed methods, Medford is limited to methods for treatment and detection of disorders mediated by vascular cell adhesion molecule (VCAM) (see, Medford at col. 4, lines 28-29). In particular, Medford discloses that VCAM expression is induced by both polyunsaturated fatty acids and hydroperoxides of polyunsaturated fatty acids (see, Medford at col. 3, lines 27-34). Medford does not disclose that only oxidized fatty acids should be detected as the Examiner may be suggesting. Instead, Medford teaches that both non-oxidized and oxidized fatty acids can induce VCAM expression (Medford, col. 3, lines 27-30) and both non-oxidized and oxidized fatty acids can be used to detect VCAM expression (see also, Medford at col. 4, lines 41-43). Nothing in Medford which would motivate one of skill in the art to detect oxidized as opposed to non-oxidized fatty acids.

More significantly, Medford provides no disclosure or teaching that antibodies have any catalytic role whatsoever in generating reactive oxygen species. Nothing in the Medford disclosure even suggests that reactive oxygen species such as ozone and hydrogen peroxide can be generated by any endogenous mammalian protein. Instead, one of skill in the art would merely gather from the Medford disclosure that both oxidized and non-oxidized fatty acids can induce VCAM expression and such VCAM expression is somehow linked to certain disorders.

This is not a disclosure of the claimed methods for detecting an antibody response or an antibody-generated inflammatory response.

Applicant respectfully requests withdrawal of this rejection of claims 1-20 under 35 U.S.C. § 102(b).

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date April 12, 2006 By _____
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This paper or fee is being filed on the date indicated above using the USPTO's electronic filing system EFS-Web, and is addressed to: The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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